

REMARKS

The examiner has rejected all of the pending claims, claims 1-7, as anticipated or obvious in view of the Chinese patent (CN 1161971) (translated). Applicants respectfully traverse.

The Chinese patent states that its invention is a crystalline form of azithromycin that is not a dihydrate. It describes only one crystalline form of azithromycin having the specific properties set forth on pages 2-4 of the Chinese patent. This crystalline form cannot contain an organic solvate in its unit cell, however, because the process used to obtain the hydrate is “a mixture of a water-soluble organic solvent and water.” See p. 4, l. 1. In fact, 10 solvents and mixtures thereof are described. See p. 4, 4th paragraph. In other words, any organic solvent can be used.

Example 1, for instance, uses only acetone. Since Example 1 does not use any ethanol, the product of example 1 cannot be an ethanolate. See attached Aronhime Declaration, ¶ 5. Therefore, since the Chinese patent describes only one crystalline form, Example 2, in which the organic solvent is a mixture of acetone and ethanol, cannot be an ethanolate. Aronhime Declaration, ¶ 6.

It is well known in the art that various crystalline forms of compounds can be formed from an organic solvent without the organic solvent becoming part of the crystalline structure, i.e., a solvate.¹ Aronhime Declaration, ¶ 4. Thus, the underlying premise of anticipation rejection – that the product of crystallization from a mixture of acetone and ethanol necessarily contains both acetone and ethanol in the crystalline structure – is not only unsupported, but is in fact contradicted by fact that the same crystalline form was prepared using only acetone and no ethanol.

Likewise, the incorrect underlying premise of the obviousness rejection is that crystallizing azithromycin from ethanol necessarily results in a solvate of ethanol. The process described in the Chinese patent, which is different from that described in present application, cannot produce an ethanolate because the same product can be prepared without any ethanol.

Applicants therefore respectfully request withdrawal of the rejections.

¹ As used herein, the meaning of “solvate” is intended not to include hydrates.